also recommends that microbiological information be obtained in at least one of the controlled studies. This draft guidance discusses patient-reported outcome instruments for assessing clinical response, and the use of time to resolution as a possible approach to assessing the primary endpoint in clinical studies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on developing drugs for the treatment of acute bacterial otitis media. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under 0910–0014; the collections of information in 21 CFR part 314 have been approved under 0910–0001; and the collections of information referred to in the guidance Establishment and Operation of Clinical Trial Data Monitoring Committees have been approved under 0910–0581.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 11, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–835 Filed 1–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Ryan White HIV/AIDS Program Core Medical Services Waiver Application Requirements (OMB No. 0915–0307): Extension

Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Ryan White HIV/AIDS Program) requires that grantees expend 75 percent of Parts A, B, and C funds on core medical services, including antiretroviral drugs, for individuals with HIV/AIDS identified and eligible under the legislation, effective fiscal year 2007. In order for grantees under Parts A, B, and C to be exempted from the 75 percent core medical services requirement, they must request and receive a waiver from HRSA, as required in the Act.

Grantees must submit a waiver request with the annual grant application containing the information and documentation which will be utilized by HRSA in making determinations regarding waiver requests.

The estimated annual burden is as follows:

Application	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Waiver Request	20	1	20	6.5	130
Total	20	.....	20	.....	130

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: January 14, 2008.

Caroline Lewis,

Associate Administrator for Management.

[FR Doc. E8–879 Filed 1–17–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice

is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Initial Review Group, Genome Research Review Committee.

Date: March 6, 2008.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH/NHGRI Twinbrook Conference Room, 5635 Fisher's Lane, Suite 4076, MSC 9306, Bethesda, MD 20852 (Telephone Conference Call).

Contact Person: Rudy Pozzatti, PhD., Scientific Review Officer, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, (301) 402–0838.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel, SEP ZHG1 HGR–P (M1).

Date: March 7, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, Double Tree Name Changed, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Rudy O. Pozzatti, PhD., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, MSC 9306, Rockville, MD 20852, (301) 402–0838, *pozzattr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS).

Dated: January 11, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 08–160 Filed 1–17–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Biodefense Therapeutics.

Date: February 11–13, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate contract proposals.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ellen S. Buczko, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 310–451–2676, *ebuczko1@niaid.nih.gov.*

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group, Microbiology and Infectious Diseases B Subcommittee.

Date: February 13–14, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Gary S. Madonna, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–496–3528, *gm12w@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 11, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 08–156 Filed 1–17–08: 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel.

Date: February 15, 2008.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Rebecca Wagenaar Miller, PhD, Scientific Review Officer, Scientific Review Branch, National Inst of Dental & Craniofacial Research, National Institutes of Health, 45 Center Dr. Rm 4AN 32G, Bethesda, MD 20892, (301) 594–0652, *rwagenaa@mail.nih.gov.*

Name of Committee: NIDCR Special Grants Review Committee.

Date: February 21–22, 2008.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Raj K Krishnaraju, PhD, MS, Scientific Review Officer, Scientific Review Branch, National Inst of Dental & Craniofacial Research, National Institutes of Health, 45 Center Dr. Rm 4AN 32J, Bethesda, MD 20892, (301) 594–4864, *kkrishna@nidcr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: January 11, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 08–157 Filed 1–17–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice